

**GENTLE LAXATIVE- bisacodyl tablet, coated**  
**Topco Associates, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Topcare 44-327**

***Active ingredient (in each tablet)***

Bisacodyl USP, 5 mg

***Purpose***

Stimulant laxative

***Uses***

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

***Warnings***

**Do not use**

if you cannot swallow without chewing.

**Ask a doctor before use if you have**

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

**When using this product**

- do not use within 1 hour after taking an antacid or milk
- do not chew or crush tablet(s)
- you may have stomach discomfort, faintness and cramps

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

### ***Directions***

- take with a glass of water

adults and children 12 years and over	take 1 to 3 tablets in a single daily dose
children 6 to under 12 years	take 1 tablet in a single daily dose
children under 6 years	ask a doctor

### ***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- avoid excessive humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

### ***Questions or comments?***

**1-888-423-0139**

### ***Principal display panel***

**+TopCare®**  
Health

NDC 36800-327-56

COMPARE TO  
DULCOLAX® LAXATIVE  
TABLETS ACTIVE  
INGREDIENT\*

**Gentle  
Laxative**

BISACODYL USP 5 mg • STIMULANT LAXATIVE

**Gentle, Dependable Constipation Relief**

**25 ENTERIC COATED TABLETS**

actual  
size

**TAMPER EVIDENT: DO NOT USE IF  
PACKAGE IS OPENED OR IF BLISTER  
UNIT IS TORN, BROKEN OR SHOWS  
ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by  
Sanofi-Aventis Deutschland GMBH, owner of the registered  
trademark Dulcolax® Laxative Tablets.

50844      ORG011932756

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ELK GROVE VILLAGE, IL 60007

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QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

QUALITY GUARANTEED

**+TopCare®**  
health

# Gentle Laxative

BISACODYL USP 5 mg • STIMULANT LAXATIVE



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NDC 36800-327-56

**+TopCare®**  
health

COMPARE TO  
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E1029

# Gentle Laxative

BISACODYL USP 5 mg • STIMULANT LAXATIVE

Gentle, Dependable Constipation Relief

**25** ENTERIC COATED  
TABLETS

actual  
size

**Drug Facts (continued)**  
*Questions or comments?*  
1-888-423-0139

**Drug Facts (continued)**  
sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

B-1910-327-56-R  
ORG011932756

**Inactive ingredients**  
acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, number

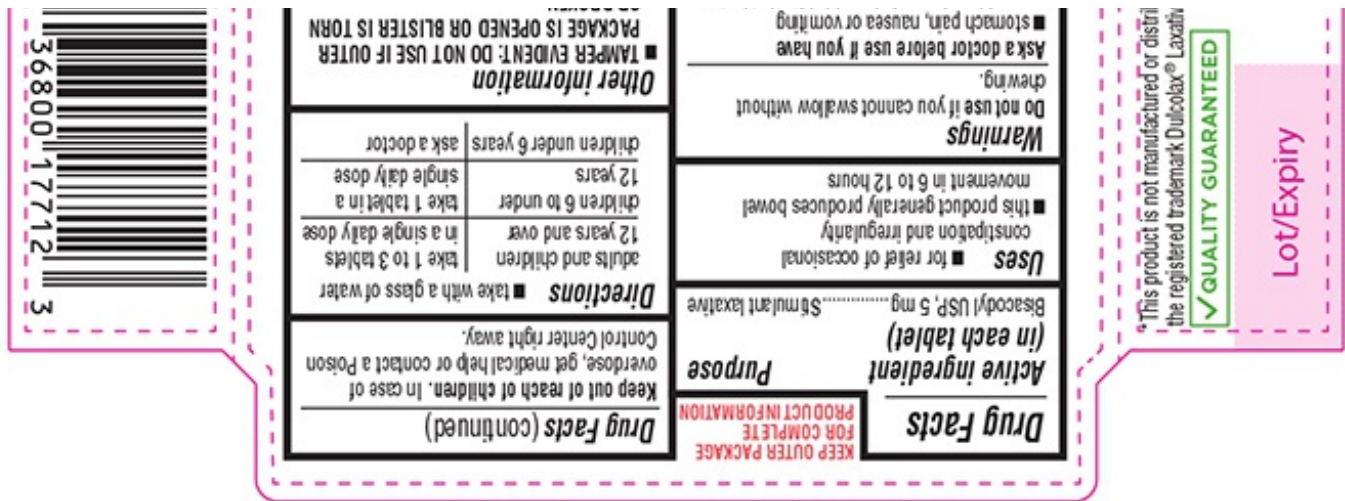
OR BROKEN  
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Stop use and ask a doctor if  
■ you have rectal bleeding or fail to have a bowel movement after use of a laxative.  
These could be signs of a serious condition.  
■ you need to use a laxative for more than 1 week  
If pregnant or breast-feeding, ask a health professional before use.

distributed by Sanofi-Aventis Deutschland GmbH, owner of  
50844 ORG011932756  
the tablets.

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topcare@topco.com  
www.topcarebrand.com



### Topcare 44-327

## GENTLE LAXATIVE

bisacodyl tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-327
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

### Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	5
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-327-03	1 in 1 CARTON	05/15/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-327-56	1 in 1 CARTON	05/15/2019	
2		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/15/2019	

**Labeler** - Topco Associates, LLC (006935977)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-327)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(36800-327)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-327)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-327)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(36800-327)

Revised: 4/2021

Topco Associates, LLC